

COVER PAGE INFORMED CONSENT FORM

Official title:

Effects of ultrasound-guided bilateral suprazygomatic maxillary nerve block on postoperative pain after elective bimaxillary osteotomy in adult patients

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Title of the investigation:

Effects of ultrasound-guided bilateral suprazygomatic maxillary nerve block on postoperative pain after elective bimaxillary osteotomy in adult patients

Code: **2TDGM**

The investigators have requested your participation in a research study. Before deciding if you agree to participate, it is important that you understand the reasons why the research is being conducted, how your information will be used, what the study will consist of and the possible benefits, risks and discomforts that may result. In the case of participating in any other study, you must inform the person responsible to assess if you can participate in it, since a patient can only participate in a study.

Background and current status of the subject: **“Effects of ultrasound-guided bilateral suprazygomatic maxillary nerve block on postoperative pain after elective bimaxillary osteotomy in adult patients”.**

Shortly, you will undergo a maxillofacial surgery that requires postoperative pain control at a multidisciplinary level by the Anesthesiology team and the Maxillofacial Institute of Teknon Medical Center. It is proposed to participate in a comparative study where no usual practice of the surgical procedure is changed or the postoperative period is lengthened. Patients will be assigned to two groups randomly to receive different pharmacological measures to reduce postoperative pain.

For pain control, a multimodal approach is recommended, and the use of loco-regional anesthesia is essential. We propose the application of a long-acting

local anesthetic in an ecological way in the course of the maxillary nerve below the zygomatic arch once the patient is under general anesthesia, before beginning the surgical approach.

Bimaxillary osteotomy is a frequent and potentially painful surgery in adults. Bimaxillary surgery under general anesthesia is the common practice. And isolated peripheral nerve blocks are widely used. These minor blockages are used to avoid the undesired effects of anesthetics and analgesics; particularly the adverse respiratory effects of opioids. The practice of loco-regional anesthesia therefore provides a control of perioperative pain in a multimodal manner showing effective postoperative analgesia and minimizing respiratory depression due to excess opioid use.

In general, bimaxillary surgery is performed pre-incisional infiltrations with a local anesthetic (LA) of short action performed by the same surgeon for the blockage of isolated peripheral nerves (maxillary and mandibular nerves via intraoral and intranasal).

The investigators now propose the application of an AL of longer action around the maxillary nerve before giving its nerve branches that provide the sensitivity of the skin of the cheek, the lower eyelid, the wing of the nose, the upper lip, the mucosa of the lower part of the nasal cavity, the dental roots and the gums of the maxilla. All this allows the investigators to optimize the control of postoperative pain.

The control of postoperative pain is a primary factor to achieve greater patient satisfaction, better rehabilitation and shorter hospital stay. The current clinical guidelines recommend the management of postoperative pain control in a multimodal manner; and this includes the practice of loco-regional anesthesia.

The purpose of the study

To determine if performing an infiltration with local anesthetic with prolonged action on the maxillary nerve below the zygomatic arch in an ultrasound-guided manner after the induction of a general anesthetic and before starting the surgical incision decreases the intra and postoperative pain, and improves the patient comfort in the first 18 postoperative hours.

Do I have an obligation to participate?

The decision about whether or not to participate in the research study is yours. In the case of not wanting to participate or of wanting to leave this study, the quality of the assistance you will receive will not be affected and the usual medical protocols will be followed. If you decide to participate, you will be given the informed consent document to sign.

What will happen if I agree to participate?

The scientific team of the present study will analyze and collect the data referring to the surgery that you have received. To assess the effectiveness of local anesthetic infiltration before awakening it will be necessary to assess the following parameters:

- Pain registration in the first postoperative 18 hours
- Registration of the administration of opioid drugs in the first postoperative 18 hours
- Registration of nausea and vomiting in the first postoperative 18 hours
- Compilation of adverse effects

What are the possible adverse effects, risks and discomforts associated with participation?

The surgical procedure itself (orthognathic surgery) will be the same regardless of your participation in the study. The anesthetic procedure will imply that once you are asleep, you can apply a long-acting local anesthetic to the path of the maxillary nerve below the zygomatic arch in a bilateral way, with the risk of vascular and nerve puncture, which is minimized by the use of the ultrasonography continuously

What are the possible benefits of participating?

To help the scientific community to determine if the long-acting local anesthetic infiltration in the path of the maxillary nerve below the zygomatic arch before the

surgical incision improves the patients' comfort during the surgery and in the first 18h after being operated on

How will my data be used in the study?

This will be adjusted according to the provisions of Organic Law 15/1999, of December 13, on the protection of personal data (LOPD), in force in Spain and for which they specify the ARCO rights (access, rectification, cancellation and opposition). of personal data. The study doctor will use your personal data for the administration and direction of the study, research and statistical analysis.

How can I establish contact if I need more information or help?

By signing this form, you agree that you have been informed of the characteristics of the study, have understood the information and the doctor has clarified all your doubts. In case of suffering a damage related to the study or to obtain an answer to any question that may arise during the investigation, please contact the persons responsible for the study: Dr Valls and Dr Molins at the Maxillofacial Institute Quiron-Teknon.

INFORMED CONSENT

Me, Mr./Mrs./Miss:

- I have received verbal information about the study and have read the attached written information, from which I have received a copy.
- I have understood what has been explained to me.
- I have been able to comment on the study and ask questions of the responsible professional.
- I give my consent to take part in the study and I assume that my participation is totally voluntary.
- I understand that I may withdraw at any time without affecting my future medical assistance.
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By signing this informed consent form, I give my consent so that my personal data can be used as described in this consent form, which complies with the provisions of Organic Law 3/2018, of December 5, of Protection of Personal Data and guarantee of digital rights. "It is the adaptation to the Spanish legal order of Regulation (European Union) 2016/679 of the European Parliament and the Council of April 27, 2016

I understand that I will receive a copy of this informed consent form.

Signature of patient

Date

Identification Document (ID) number

DECLARATION BY THE INVESTIGATOR

The patient or patient signing this consent form has received, on the part of the professional, detailed information in oral and written form of the process and nature of this research study, and has had the opportunity to ask any questions regarding the nature , the risks and benefits of your participation in this study

Signature of investigator

Date

Gloria Molins MD, MSc

A handwritten signature in black ink, appearing to be 'G. Molins', written in a cursive style.